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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,884	10/24/2005	Bengt E B Sandberg	05822.0320USWO	9220

23552 7590 12/29/2010

MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
TONGUE, LAKIA J	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
12/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,884	SANDBERG ET AL.	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12 and 14-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12 and 14-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 2010 has been entered. Claim 11, 24 and 25 have been amended. Claims 26-30 have been added. Claims 11, 12 and 14-30 are pending and currently under examination.

Rejections Withdrawn

2. In view of Applicant's amendment to the claims, the rejection of claims 11, 12 and 14-24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the use of the phrase "EP 1997 test protocol is fulfilled" is withdrawn.

3. In view of Applicant's amendment to claim 11, the rejection of claims 11, 12, 14-21, 23 and 24 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Huth et al. (US 2003/0100101 A1; Filing date 6/27/02) is withdrawn.

New Grounds of Objection and Rejection

Claim Objections

4. Claims 23-25 are objected to because of the following informalities: Claim 24 recites "or organism" in line 3 of said claim. The Examiner believes this may be a typo and request clarification via an amendment or a response. Further, both claims 24 and 25 recite limitations such as "recovered at 7 day" or "recovered at 14 days" in lines 3 and 4 of said claims. It is suggested that Applicant amend said claims to recite, for example, "recovered at day 7" or "recovered at the 14th day". Lastly, claim 23 recites "at least 6 h", to be consistent with the format of claims 24 and 25, the Examiner is suggesting that Applicant amend "h" to "hours". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is rendered vague and indefinite by the use of the phrase "bacteria are reduced by at least log 2 at 6 hours, log 3 at 24 hours, with or organism recovered at 7 day and thereafter". It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. The method ultimately intends to reduce the microbial content of a matrix. It is unclear what Applicant intends by "with organism recovered at

7 day and thereafter". Does Applicant intend that no organism be recovered at day 7 and there after or does Applicant intend for Applicant to recover an organism at day 7 and thereafter? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 11, 12, 14-25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ofsthun et al. (U.S. Patent 5,868,936; Publication: 2/9/99) and Huth et al. (US 2003/100101 A1; filed: 6/27/02).

Independent claim 11 is drawn to a method of producing a separation matrix with eliminated or reduced microbial content, comprising steps of: providing a microbially contaminated separation matrix, in a housing or container; wherein the microbially contaminated separation matrix comprises a polymeric porous material in beaded form, a microfiltration hollow-fiber, or a flat sheet membrane, and wherein the separation matrix comprises immobilized ligand; adding an aqueous antimicrobial preservation composition, which comprises at least one alkyl paraben, to said separation matrix in said housing or container; allowing said aqueous antimicrobial preservation composition to exert its effect in said housing or container until the number of colony forming units

per g preservative composition is sufficiently reduced; and rinsing said aqueous antimicrobial preservation composition from said housing or container to provide the separation matrix with eliminated or reduced microbial content and containing the immobilized ligand.

Ofsthun et al. disclose an affinity membrane device for the selective removal of targeted molecules contained in plasma or blood. The simplified but effective affinity membrane device of the present invention has an elongated housing having an inlet port and an outlet port for entry and exit of blood therefrom. Additionally, the membrane device includes hollow fibers with pores encased inside the housing. The pores also have ligand immobilized on an interior surface of the pores; the ligand has an affinity for and binds the targeted molecule present in the plasma being transported into the pores of the hollow fibers. In another embodiment, the ligand may be an enzyme that can modify and release the targeted molecule (see column 3, lines 11-31). Moreover, Ofsthun et al. disclose immobilization techniques that provide significant advantages over prior procedures. In one embodiment, an avidin/biotin complex is utilized for immobilization of the ligand to the pore surface. Alternatively, a polyethylene glycol immobilization technique can be utilized either independently or in conjunction with an avidin/biotin complex (see column 7, lines 25-32). Ofsthun et al. disclose that the hollow fiber membrane of the present invention is advantageously made of a blood compatible material which results in lower complement activation during treatment. Suitable fiber materials are cellulose triacetate, polysulfone, polyacrylonitrile, ethylene/vinyl alcohol copolymer, polymethylmethacrylate, polyamide,

polypropylene, cellulose acetate, regenerated cellulose, polycarbonate, polyethylene, polyvinylalcohol, polyvinylchloride and the like (see column 7, lines 59-67).

Ofsthun et al. do not specifically disclose that the method comprises the step of adding an aqueous antimicrobial preservation composition comprising at least one alkyl paraben, to said separation matrix in said housing or container or rinsing said aqueous antimicrobial preservation composition from said housing or container to provide the separation matrix with eliminated or reduced microbial content and containing the immobilized ligand.

Huth et al. disclose simultaneous cleaning and decontaminating compositions and methods of using them to disinfect a medical device prior to reuse. Cleaning the device can be expected to destroy microorganisms (see paragraph 0009). Standards for sterilization are based upon the known or possible risk of contamination of a particular medical device by a particular microorganism, the pathogenic nature of the organism and other principles in infection control (see paragraph 0012). Moreover, Huth et al. disclose that kidney dialyzers require particular cleaning and disinfection solutions because of the types of components the dialyzers use, which include: (1) coil, which incorporates a membrane in the form of a flattened tube wound around a central, rigid cylinder core, with a supporting mesh between adjacent portions of the membranes; (2) parallel plate, which incorporates a membrane in tubular or sheet form supported by plates in a sandwiched configuration; and (3) hollow-fiber, which incorporates the semi permeable membrane in the form of the walls of very small fibers having a microscopic channel running through them (see paragraph 0018; the Examiner

is equating this to the microbially contaminated separation matrix comprising a microfiltration hollow-fiber or a flat sheet membrane). Huth et al. disclose that there are several advantages to disinfection and reuse of a dialyzer, which include cost savings with dialyzer reuse and health advantages because reused dialyzers significantly mitigate patients "new dialyzer" symptoms as well as immune reactions that often occur. The inherent clinical advantage of reused dialyzers has been attributed to the reduction in trace contamination and to the masking of immune reaction sites located on the membrane surface by protein deposits (see paragraph 0021). Huth et al. disclose that dialyzer reprocessing involves three basic steps: (1) cleaning, (2) dialysis efficacy confirmation, and (3) high-level disinfecting involving soak times long enough to achieve sterilization. The cleaning step involves removing residual blood, organic and cellular material from the blood side and removing dialysate from the dialysate side of the semi permeable membrane (see paragraph 0022). The chemical disinfecting agent must be able to be rinsed out of the dialyzer (see paragraph 0029).

Moreover, Huth et al. disclose that preservatives may be added to the formulas of the present invention, particularly to a separate liquid enzyme formula to preserve the solution against contamination from microorganisms such as bacteria, yeasts and fungi. EDTA may be employed, with a preferred concentration of 0.05%-0.10% $^{w/v}$ in the formula requiring preservation. Huth et al. disclose that EDTA as well as other common preservatives such as methyl paraben (methyl 4-hydroxy benzoate about 0.1% $^{w/v}$), benzyl-4-hydroxybenzoate, ethyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate and butyl-4-hydroxybenzoate can be employed as preservatives. Preservatives may be

used alone or in combination (see paragraph 0123). Huth et al. disclose adding propylene glycol to the formulation. Huth et al. disclose that concentrations of glycols between 20% $^{w/v}$-70% $^{w/v}$ are preferred, although lower or higher concentrations may be employed (see paragraph 0086).

Huth et al. do not specifically disclose the specific concentrations of methyl paraben (claim 14), ethyl paraben (claim 15), propyl paraben (claim 16), butyl paraben (claim 17), and propylene glycol (claim 20); that the sterilization of the antimicrobial preservation composition occurs before it is added to the separation matrix (claim 21); that the preservation composition is steam or filter sterilized (claim 22); or that the antimicrobial preservation composition is allowed to exert its effect for at least 6 hours or until bacteria are reduced by at least log 2 at 6 hours, log 3 at 24 hours, with organism recovered at 7th day and thereafter, and yeast/moulds reduced by at least log 2 at 7th day with no increase thereafter (claim 24); or that the antimicrobial preservation composition is allowed to exert its effect until bacteria are reduced by at least log 1 at 24 hours, log 3 at the 7th day, with no increase recovered at the 14th day and thereafter, and yeast/moulds reduced by at least log 1 at the 14th day with no increase thereafter (claim 25).

With regard to the limitations of claims 24 and 25, the method steps of the instant invention are identical to the method steps set forth in the prior art. Absent evidence to the contrary, the antimicrobial preservation composition would necessarily have bacteria reduced by at least log 2 at 6 hours, log 3 at 24 hours, yeast/moulds reduced by at least log 2 at the 7th day with no increase thereafter, reduced by at least log 1 at

24 hours, log 3 at the 7th day, with no increase recovered at the 14th day and thereafter, and yeast/moulds reduced by at least log 1 at the 14th day with no increase thereafter.

Limitations such as the concentration of a paraben, when to sterilize and the type of sterilization method used to sterilize an aqueous antimicrobial preservative, as well as the amount of time an antimicrobial preservation composition is allowed to exert are being viewed as limitations of optimizing experimental parameters.

Regarding the specific concentrations listed in the instant claims, MPEP 2144.05 states, "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert.*

denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997)."

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the extracorporeal device of Ofsthun et al. with the teachings of Huth et al. because there are several advantages to disinfection and reuse of a dialyzer, which include cost savings with dialyzer reuse and health advantages because reused dialyzers significantly mitigate patients "new dialyzer" symptoms as well as immune reactions that often occur. The inherent clinical advantage of reused dialyzers has been attributed to the reduction in trace contamination and to the masking of immune reaction sites located on the membrane surface by protein deposits (see Huth et al., paragraph 0021). Further it would have been prima facie obvious to use paraben in said invention because it is an antimicrobial preservative that inhibits or retards microbial growth when an effective amount is added to a medium capable of supporting undesirable microbial growth, therefore it would be effective for eliminating or reducing microbial content.

It would have been expected barring evidence to the contrary that the method would be effective for producing a separation matrix. The claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art (*KSR International Co. v. Teleflex Inc.*, 550 U.S.-, 82 USPQ2d 1385 (2007).

7. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ofsthun et al. (U.S. Patent 5,868,936; Publication: 2/9/99) and Huth et al. (US

2003/100101 A1; filed: 6/27/02) as applied to claims 11, 12, 14-25 and 28-30 above, and further in view of Sandberg et al. (U.S. 2002/0159994 A1).

Claims 26 is drawn to a method of producing a separation matrix with eliminated or reduced microbial content, comprising steps of: providing a microbially contaminated separation matrix, in a housing or container; wherein the microbially contaminated separation matrix comprises a polymeric porous material in beaded form, a microfiltration hollow-fiber, or a flat sheet membrane, and wherein the separation matrix comprises immobilized ligand; adding an aqueous antimicrobial preservation composition, which comprises at least one alkyl paraben, to said separation matrix in said housing or container; allowing said aqueous antimicrobial preservation composition to exert its effect in said housing or container until the number of colony forming units per g preservative composition is sufficiently reduced; and rinsing said aqueous antimicrobial preservation composition from said housing or container to provide the separation matrix with eliminated or reduced microbial content and containing the immobilized ligand, wherein the separation matrix comprises polysaccharide gel (i.e. agarose, as recited in claim 27).

Ofsthun et al. disclose an affinity membrane device for the selective removal of targeted molecules contained in plasma or blood. The simplified but effective affinity membrane device of the present invention has an elongated housing having an inlet port and an outlet port for entry and exit of blood therefrom. Additionally, the membrane device includes hollow fibers with pores encased inside the housing. The pores also have ligand immobilized on an interior surface of the pores; the ligand has

an affinity for and binds the targeted molecule present in the plasma being transported into the pores of the hollow fibers. In another embodiment, the ligand may be an enzyme that can modify and release the targeted molecule (see column 3, lines 11-31). Moreover, Ofsthun et al. disclose immobilization techniques that provide significant advantages over prior procedures. In one embodiment, an avidin/biotin complex is utilized for immobilization of the ligand to the pore surface. Alternatively, a polyethylene glycol immobilization technique can be utilized either independently or in conjunction with an avidin/biotin complex (see column 7, lines 25-32). Ofsthun et al. disclose that the hollow fiber membrane of the present invention is advantageously made of a blood compatible material which results in lower complement activation during treatment. Suitable fiber materials are cellulose triacetate, polysulfone, polyacrylonitrile, ethylene/vinyl alcohol copolymer, polymethylmethacrylate, polyamide, polypropylene, cellulose acetate, regenerated cellulose, polycarbonate, polyethylene, polyvinylalcohol, polyvinylchloride and the like (see column 7, lines 59-67).

Huth et al. disclose simultaneous cleaning and decontaminating compositions and methods of using them to disinfect a medical device prior to reuse. Cleaning the device can be expected to destroy microorganisms (see paragraph 0009). Standards for sterilization are based upon the known or possible risk of contamination of a particular medical device by a particular microorganism, the pathogenic nature of the organism and other principles in infection control (see paragraph 0012). Moreover, Huth et al. disclose that kidney dialyzers require particular cleaning and disinfection solutions because of the types of components the dialyzers use, which include: (1) coil,

which incorporates a membrane in the form of a flattened tube wound around a central, rigid cylinder core, with a supporting mesh between adjacent portions of the membranes; (2) parallel plate, which incorporates a membrane in tubular or sheet form supported by plates in a sandwiched configuration; and (3) hollow-fiber, which incorporates the semi permeable membrane in the form of the walls of very small fibers having a microscopic channel running through them (see paragraph 0018; the Examiner is equating this to the microbially contaminated separation matrix comprising a microfiltration hollow-fiber or a flat sheet membrane). Huth et al. disclose that there are several advantages to disinfection and reuse of a dialyzer, which include cost savings with dialyzer reuse and health advantages because reused dialyzers significantly mitigate patients "new dialyzer" symptoms as well as immune reactions that often occur. The inherent clinical advantage of reused dialyzers has been attributed to the reduction in trace contamination and to the masking of immune reaction sites located on the membrane surface by protein deposits (see paragraph 0021). Huth et al. disclose that dialyzer reprocessing involves three basic steps: (1) cleaning, (2) dialysis efficacy confirmation, and (3) high-level disinfecting involving soak times long enough to achieve sterilization. The cleaning step involves removing residual blood, organic and cellular material from the blood side and removing dialysate from the dialysate side of the semi permeable membrane (see paragraph 0022). The chemical disinfecting agent must be able to be rinsed out of the dialyzer (see paragraph 0029).

Moreover, Huth et al. disclose that preservatives may be added to the formulas of the present invention, particularly to a separate liquid enzyme formula to preserve the solution against contamination from microorganisms such as bacteria, yeasts and fungi. EDTA may be employed, with a preferred concentration of 0.05%-0.10% $^{w/v}$ in the formula requiring preservation. Huth et al. disclose that EDTA as well as other common preservatives such as methyl paraben (methyl 4-hydroxy benzoate about 0.1% $^{w/v}$), benzyl-4-hydroxybenzoate, ethyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate and butyl-4-hydroxybenzoate can be employed as preservatives. Preservatives may be used alone or in combination (see paragraph 0123). Huth et al. disclose adding propylene glycol to the formulation. Huth et al. disclose that concentrations of glycols between 20% $^{w/v}$-70% $^{w/v}$ are preferred, although lower or higher concentrations may be employed (see paragraph 0086).

The combination of references do not specifically disclose that the separation matrix is a polysaccharide gel or agarose.

Sandberg et al. disclose extracorporeal devices that comprise flat sheet membranes and as a preferred embodiment a matrix comprising agarose (see paragraph 0040).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the extracorporeal device of Ofsthun et al. and with the teachings of Sandberg et al. because polysaccharide gel, specifically, agarose is a polymeric porous material commonly used to measure microorganism motility and mobility, which will allow one of skill in the art the ability to measure whether or not the

separation matrix eliminated or reduced microbial content.

The substitution for one known matrix for another would have yielded predictable results to one of ordinary skill in the art at the time of invention. It would have been expected barring evidence to the contrary that the method would be effective for producing a separation matrix. The claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art (*KSR International Co. v. Teleflex Inc.,* 550 U.S.-, 82 USPQ2d 1385 (2007).

Pertinent Prior Art

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Schoenberg (US. Patent 5,037,843); Jungbauer et al. (Journal of Chromatography B, 1994; 662: 143-179); and Vigo (Chapter 11, American Chemical Society, 2001: 175-200).

Conclusion

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Duffy can be reached on 571-272-0855. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT
12/16/10

/Vanessa L. Ford/

Primary Examiner, Art Unit 1645